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UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
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Washington, D.C. 20231

Joseph F. DiPrima  
MERCK & CO., INC.  
P.O. BOX 2000  
RAHWAY, NEW JERSEY 07065-0907

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,797,413

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,797,413, which claims the human drug product TRUSOPT®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,233 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 14, 1996 (61 Fed. Reg. 24317). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,736) + 365 \\ &= 1,233 \text{ days (3.4 years)}\end{aligned}$$

Since the regulatory review period began March 11, 1989, after the patent issue date (January 10, 1989), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the 14 year exception of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,233 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,797,413
Granted	:	January 10, 1989

Original Expiration Date : December 12, 2004<sup>1</sup>

Applicant : John J. Baldwin et al.

Owner of Record : Merck & Co., Inc.

Title : THIENO THIOPYRAN SULFONAMIDE  
DERIVATIVES, PHARMACEUTICAL  
COMPOSITIONS AND USE

Classification : 514/432

Product Trade Name : TRUSOPT®

Term Extended : 1,233 days

Expiration Date of Extension : April 28, 2008

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

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<sup>1</sup> The term of the patent subsequent to the expiration date of U.S. Patent No. 4,677,115 has been disclaimed. U.S. Patent No. 4,677,115 issued June 30, 1987 from an application that claimed priority under 35 U.S.C. § 120 to an application filed on December 12, 1984. Accordingly, the original expiration date of U.S. Patent No. 4,797,413 is December 12, 2004.

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.



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Hiram H. Bernstein  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: TRUSOPT®  
FDA Docket No.: 95E-0408